

REMARKS

Applicants respectfully request entry of the present amendments to the claims and consideration of the following remarks.

STATUS OF CLAIMS

Claims 1-42 are pending. Claims 1-6, 19-21, and 30-42 are directed to the elected species of hydroxypropyl methylcellulose as a coating for the capsule body and cap. Thus, claims 7-18 and 22-29 are withdrawn. In the Office Action, claim 6 was said to have been withdrawn; however, this is in error. Claim 6 is directed to the elected species, and should not be deemed to have been withdrawn from consideration.

Please be kind enough to correct your records.

Claim 1 is amended and claims 20 and 21 are canceled. Support for the amendment to claims 1 may be found throughout the specification, for example, at page 5, lines 8-22; in the Examples; and in original claim 21. No new matter has been added.

REJECTIONS UNDER § 102(B) AND (E)

It is axiomatic that, in order for a reference to properly be said to anticipate a claim under Section 102 of the Patent Act, the reference must disclose, within its four corners, each and every limitation of the claim. As will be shown, the Section 102 rejections are not well taken because the cited reference in each case fails to disclose at least one limitation of each of the claims to which they were applied.

Claims 1-3 and 39 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by the article of Bauer and Fuhrer, page 320, Figure 14.41, 1999. This rejection is respectfully traversed.

Claim 1 is directed to a modified release pharmaceutical composition in the form of a capsule which comprises, among other things, a coated capsule body and a coated or uncoated capsule cap. When the capsule cap is coated, the coating thicknesses of the capsule body and cap are different. Bauer and Fuhrer do not disclose this. They describe a hard gelatin capsule. There is no mention of a coating, much less a coated

capsule body and a coated or uncoated capsule cap. Since there is no mention of coating parts of capsules, there is, by definition, no mention of coating capsule bodies and capsule caps differently or with different coating thicknesses. Therefore, claim 1 and all its dependents are novel over Bauer and Fuhrer.

Claims 1-5 and 30-42 (and presumably 6) were rejected under 35 U.S.C. § 102(e) as allegedly anticipated by US 7,163,693 (Clarke). This rejection is respectfully traversed.

Claim 1 is directed to a modified release pharmaceutical composition in the form of a capsule which comprises, among other things, a coated capsule body and a coated or uncoated capsule cap. When the capsule cap is coated, the coating thicknesses of the capsule body and cap are different.

Clarke discloses what is said to be a multi-component pharmaceutical dosage device having multiple drug substance-containing compartments. While each of Clarke's so-called compartments may have "different characteristics," nothing is said in Clarke about a coated capsule body and a coated or uncoated capsule cap, as called for in present claim 1. Therefore, claim 1 and all its dependents are plainly novel over Clarke.

REJECTIONS UNDER § 103(A)

Claims 19-21 were rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Clarke in view of US 2001/0036473 (Scott). This rejection is respectfully traversed.

Claim 20 is canceled; therefore, the rejection with respect to this claim is moot. Claim 19 is dependent upon independent claim 1. Claim 1 is amended to incorporate the limitations of claim 21. Claim 1 was discussed above. It calls for a modified release pharmaceutical composition in the form of a capsule which comprises, among other things, a coated capsule body and a coated or uncoated capsule cap. When the capsule cap is coated, the coating thicknesses of the capsule body and cap are different.

Clarke was discussed above. Suffice it to say that Clarke does not show or describe a coated capsule body and a coated or uncoated capsule cap, as called for in present claim 1.

Scott describes a special type of a coated capsule for drug delivery to the small intestine or colon. However, Scott teaches that the capsule should be filled, assembled, sealed, and then fully coated. (See par [0019], [0037]-[0041], [0043]-[0046]. When coated according to Scott's teaching, any "capsule cap" would be coated just like the capsule body. Nothing in Scott suggests that a coated capsule body and a cap, if coated, have coatings of different thicknesses according to present claim 1. There is no apparent motivation or suggestion as to why a person of ordinary skill would set about to try to combine the teachings or disclosures of Clarke and Scott in the first place, but even if they did, they would not be led to the concept of differential coating thickness for capsule bodies and caps accordingly to claim 1 and its dependents, or any of Applicants' other claims.

Therefore, the present independent claim 1 and its dependents (as well as all other pending claims) are nonobvious and patentable over Clarke in view of Scott.

In view of the foregoing amendments and remarks, Applicants respectfully request favorable reconsideration of this application and early notice of allowance of all pending claims.

FEES

The undersigned believes that no fees are due in connection with this filing. However, if any fees are due the Commissioner is hereby authorized to charge any fee deficiencies or credit any fee overpayments associated with this communication or application to our Deposit Account No. 12-2355. Furthermore, please grant any needed extensions of time required to enter this response, and charge any fees or additional required fees therefore to our Deposit Account No. 12-2355.

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